Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy

Protocol summary

Study aim

Determine and comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy

Design

Clinical trial phase3 with 2parallel groups, 3-sided blind, having balanced block randomization with considering gradual patient referral and sample size of 60

Settings and conduct

After obtaining written consent, patients who refers to Ali ibn Abitalib hospital for upper endoscopy, randomly assigned to 2groups of Dexmedomidine(D) and Propofol(P). Syringe of drugs will coded by an anesthetist who doesn't interfere with patient's sedation and evaluation process; it coded with a three-digit code, and patients divided according to the code for D or P group. Study is 3-sided blind, and patient, endoscopic physician, and person evaluating the symptoms are blinded to type of treatment group, and only a supervisor who prepares drugs and divides patients according to the code for each group, will know the treatment type received by patients.

Participants/Inclusion and exclusion criteria

Enter criteria:patients with elective upper gastrointestinal endoscopy with ASA class ≤3 Not-enter criteria:Having cardiovascular-liver- kidney- psychiatric disease, SBP<90, Drug Addiction, Egg and soy allergy, Emergency endoscopy

Intervention groups

In D group, Dexmedetomidine doses of 0.5µg/kg bolus and 0.7-0.5µg/Kg/hr infusion and in P group ,Propofol with doses of 0.5mg/kg bolus and 30µg/Kg/min infusion will given intravenously to patients. Patient hemodynamics will be checked and monitored from start of medication. Relaxation after taking drugs will asked using Ramsay Relaxation Scale from 0-5 (0-Restless,1-Relax,2-Sleepy,3-Confuse but Responded to Verbal Orders,4-No Response to Verbal orders,5-No Response to painful incitements) and will evaluated by an anesthesiologist. After patient becomes alert, sedation satisfaction will be asked.

Main outcome variables

Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190212042688N1**
Registration date: **2019-03-02, 1397/12/11**
Registration timing: **prospective**

Last update: **2019-03-02, 1397/12/11**
Update count: **0**

Registration date

2019-03-02, 1397/12/11

Registrant information

Name

Parnia Sayarfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5796

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dr.sf.1458@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-15, 1397/12/24

Expected recruitment end date

2019-06-14, 1398/03/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy

Public title
Comparison of Dexmedetomidine and Propofol in sedation efficacy in patients with elective upper gastrointestinal endoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with elective upper gastrointestinal endoscopy ASA class ≤3
Exclusion criteria:
Having cardiovascular disease (arrhythmia, AS, IHD, HTN, HF or EF <30%) Having liver disease (Child-Pugh Classification C) Having kidney disease (GFR <60%) Having psychiatric illness (Major Depression, Mania, Psychosis) SBP<90 Having Drug Addiction Egg and soy allergy Emergency endoscopy
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
After obtaining written consent, patients who are elective for upper endoscopy are randomly assigned to two groups that are prescribed to a group of Dexmedomidine (D) and group of Propofol (P). The syringe of drugs will coded by an anesthetist who does not interfere with the patient's sedation and evaluation process; it coded with a three-digit code, and the patients are divided according to the code for the Dexmedomidine or Propofol group. The study is three-sided blind, and the patient, the endoscopic physician, and the person evaluating the symptoms are blind to the type of treatment group, and only a supervisor who prepares the drugs, and divides patients according to the code for each groups will know the type of treatment received by the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Medical Sciences Campus, Dr. Hesabi Sq.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2019-02-22, 1397/12/03
Ethics committee reference number
IR.ZAUMS.REC.1397.455

Health conditions studied

1

Description of health condition studied
Upper gastrointestinal disorders
ICD-10 code
Z13.810
ICD-10 code description
Encounter for screening for upper gastrointestinal disorder

Primary outcomes

1

Description
Sedation
Timepoint
By monitoring, sedation will be recorded from the start of the drug administration (time 0) and every 5 minutes until the patient transferred to the recovery room.
Method of measurement
Relaxation after taking drugs will asked using Ramsay Relaxation Scale from 0-5 (0-Restless,1-Relax,2-Sleepy,3-Confuse but Responded to Verbal Orders,4-No Response to Verbal orders,5-No Response to painful incitements) and will evaluated by an anesthesiologist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexmedetomidine - In D group, Dexmedetomidine doses of 0.5µg/kg bolus and 0.7-0.5µg/Kg/hr infusion will given intravenously to patients.
Category
Treatment - Drugs

2

Description
Intervention group: Propofol - in P group ,Propofol with doses of 0.5mg/kg bolus and 30µg/Kg/min infusion will given intravenously to patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ibn Abitalib hospital of Zahedan
Full name of responsible person
Mohammad Kazem Momeni
Street address
Khalij-e-fars highway, Salamat Blvd., Ali Ibn Abitalib hospital
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http://alihos.zaums.ac.ir/#%D8%A8%DB%8C%D9%85%D8%A7%D8%B1%D8%B3%D8%AA%D8%A7%D9%86%20%D8%B9%D9%84%DB%8C%20%D8%A7%D8%A8%D9%86%20%D8%A7%D8%A8%DB%8C%D8%B7%D8%A7%D9%84%D8%A8%20(%D8%B9)

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohsen Taheri
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Web page address
http://research.zaums.ac.ir/#%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%AA%20%D8%AA%D8%AD%D9%82%D9%8A%D9%82%D8%A7%D8%AA%20%D9%88%20%D9%81%D9%86%D8%A7%D9%88%D8%B1%D9%8A
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Parnia Sayarfar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only a portion of the information, such as the original outcome information, will be shared.

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Data will only be available to researchers working in academic institutions.

Under which criteria data/document could be used
Data should only be used to get ideas in future research.

From where data/document is obtainable
Referring to the university's research deputy

What processes are involved for a request to access data/document
After the registering of request in Research deputy and passing the routine office process, documents will be available up to maximum of one week.

Comments